

REMARKS

After entry of this Amendment, the pending claims are: claims 1, 2, 4-8, 10, 15, 16, 18, 22-25, 27 and 31-39. The Office Action dated December 24, 2008 has been carefully considered. Claims 3, 9, 11-14, 17, 19-21, 26 and 28-30 have been canceled without prejudice. Claim 1 has been amended. Claim 39 has been added. No new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following remarks is respectfully requested.

In the Office Action dated December 24, 2009, Examiner Cumberledge:

- objected to claim 1 for containing an inconsistency;
- rejected claims 1, 2 and 4-8 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,488,761 to Leone ("Leone");
- rejected claim 10 under 35 U.S.C. 103(a) as being unpatentable over Leone;
- rejected claims 24, 25, 27 and 31-38 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,573,520 to Schwartz *et al.* ("Schwartz") in view of Schwartz;
- rejected claims 15, 16, 18, 22 and 23 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,672,175 to Martin in view of Schwartz and in view of Schwartz.

CLAIM OBJECTION

Independent claim 1 was objected to for containing an inconsistency. Specifically, independent claim 1 was objected to because the preamble of independent claim 1 recited “a flexible rod” while the body of the claim positively recited first and second pedicle screws thereby rendering the scope of the claim unclear.

Independent claim 1 has been amended to recite, *inter alia*, “a flexible rod for use in a spinal fixation device and for mounting between a first pedicle screw and a second pedicle screw such that the flexible rod limits movement of a first vertebra relative to a second vertebra, the flexible rod comprising a first end; a second end; and a longitudinal substantially cylindrical center section.” As such, it is believed that this objection has been overcome. Withdrawal of this objection is respectfully requested.

INDEPENDENT CLAIM 1

Independent claim 1 and claims 2 and 4-8, which are dependent therefrom, have been rejected as being anticipated by Leone. Claim 10 has been rejected as being unpatentable over Leone. Applicant respectfully traverses these rejections with respect to the above-listed claims, as amended.

Referring to Figs. 3-5, Leone discloses a reamer 20 consisting of a single coil 22. The coil 22 is made from pairs of helical slots 24 which are machined into a shaft 23. The helical slots 24 including interruptions 30. The helical slot interruptions 30 provide added strength to the shaft 23 thereby enabling the reamer 20 to operate without an inner coil. The shaft 23 preferably includes three helical slot interruptions 30 spaced evenly along the length of the shaft 23 thus dividing the helical slots 24 into four sets of slots of equal length.

Referring to Fig. 6, Leone further discloses a method for manufacturing the shaft 23. Initially, a hollow rod 40 is provided. The rod 40 is advanced along a helical path by a combination of rotational motion 42 and translational motion 44. A machine head 46 is oriented so as to machine an opening across a diameter of the rod 40. When the machine head 46 begins machining, a first helical slot begins at point 50 and a second corresponding helical slot begins at point 50', diametrically opposed to point 50. As the rod 40 advances, a pair of intertwined helical slots are formed thereon. At point 51 and diametrically opposite point 51', machining is terminated. At points 52 and 52' machining resumes and a second pair of intertwined helical slots are formed along the rod 40.

Applicant respectfully submits that Leone does not disclose each and every limitation of independent claim 1 as amended. Amended claim 1 is directed to a flexible rod for use in a spinal fixation device and for mounting between a first pedicle screw and a second pedicle screw such that the flexible rod limits movement of a first vertebra relative to a second vertebra and recites, as follows:

a first end; a second end; and a longitudinal substantially cylindrical center section having a longitudinal axis and an outer surface, the center section being located between and coupled to the first end and the second end, **the center section including a plurality of grooves formed in the outer surface of the substantially cylindrical center section, the plurality of grooves extending circumferentially around the longitudinal axis and a plurality of holes formed in the substantially cylindrical center section, each hole intersecting an end of at least two of the plurality of grooves formed in the outer surface of the rod.** (Emphasis added).

Examiner Hoffman is thanked for the courtesy extended during the In-Person Examiner Interview held on June 18, 2009. Per our discussion, Applicant respectfully submits that there is no disclosure, teaching, or suggestion in Leone of a flexible rod including a longitudinal substantially cylindrical center section including a plurality of grooves and a plurality of holes wherein each hole

intersects an end of at least two of the plurality of grooves formed in the outer surface of the rod.

Rather, at best, Leone discloses a helical slot interruption 30 or relief at the beginning and end of each helical slot. There is no disclosure that the helical slot interruption 30 intersects an end of at least two of the plurality of grooves.

Therefore, it is respectfully submitted that Leone does not disclose, teach, or suggest all of the limitations of independent claim 1. Thus, it is respectfully submitted that amended claim 1 is allowable over Leone for at least this reason. Withdrawal of this rejection and allowance of amended claim 1 is respectfully requested.

Furthermore, as claims 2, 4-8 and 10 all depend from independent claim 1, it is submitted that these claims are equally allowable for at least these reasons. Withdrawal of these rejections and allowance of claims 2, 4-8 and 10 is also respectfully requested.

NEWLY ADDED INDEPENDENT CLAIM 39

Newly added claim 39 is directed to a connection unit for use in a spinal fixation device and recites, as follows:

a first bone coupling assembly; a second bone coupling assembly; and a flexible rod including: a first end received by and coupled to the first bone coupling assembly; a second end received by and coupled to the second bone coupling assembly, the first and second bone coupling assemblies capable of securing the rod between a first vertebra and a second vertebra such that the flexible rod limits movement of the first vertebra relative to the second vertebra; and a longitudinal substantially cylindrical center section having a longitudinal axis and an outer surface, the center section being located between and coupled to the first end and the second end, **the center section including a plurality of grooves formed in the outer surface of the substantially cylindrical center section, the plurality of grooves extending circumferentially around the longitudinal axis and a plurality of holes formed in the**

substantially cylindrical center section, each hole intersecting an end of at least two of the plurality of grooves formed in the outer surface of the rod. (Emphasis added).

Examiner Hoffman is thanked for the courtesy extended during the In-Person Examiner Interview held on June 18, 2009. Per our discussion and similar to the argument presented above in connection with independent claim 1, Applicant respectfully submits that there is no disclosure, teaching, or suggestion in Leone of a flexible rod including a longitudinal substantially cylindrical center section including a plurality of grooves and a plurality of holes wherein each hole intersects an end of at least two of the plurality of grooves formed in the outer surface of the rod. Rather, at best, Leone discloses a helical slot interruption 30 or relief at the beginning and end of each helical slot. There is no disclosure that the helical slot interruption 30 intersects an end of at least two of the plurality of grooves. Therefore, it is respectfully submitted that Leone does not disclose, teach, or suggest all of the limitations of newly added independent claim 39 for at least this reason.

In addition, Applicant respectfully submits that there is no disclosure, teaching, or suggestion in Leone of a longitudinal rod including a first end received by and coupled to a first bone coupling assembly and a second end received by and coupled to a second bone coupling assembly, wherein the first and second bone coupling assemblies are capable of securing the rod between a first vertebra and a second vertebra such that the flexible rod limits movement of the first vertebra relative to the second vertebra. Rather, at best, Leone discloses a flexible reamer. Therefore, it is respectfully submitted that Leone does not disclose, teach, or suggest all of the limitations of newly added independent claim 39 for at least this reason as well.

Accordingly, it is respectfully submitted that Leone does not disclose, teach, or suggest all of the limitations of newly added independent claim 39. Thus, it is respectfully submitted that claim 39 is allowable over Leone for at least these reasons. Allowance of claim 39 is respectfully requested.

INDEPENDENT CLAIM 15

Independent claim 15 and claims 16, 18, 22 and 23, which are dependent therefrom, were rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Schwartz in further view of Schwartz. Specifically, Examiner Cumberledge indicated that Martin discloses each and every limitation of independent claim 15 but for a plurality of grooves formed in an outer surface of a rod and a plurality of tunnels formed in the rod wherein each tunnel includes a pair of diametrically opposed openings on the outer surface of the rod, the openings intersecting one of the grooves formed on the outer surface of the rod. That is, as admitted by Examiner Cumberledge, Martin does not disclose a plurality of grooves and a plurality of tunnels wherein the tunnel openings intersect one of the grooves formed on the outer surface of the rod. Rather, Examiner Cumberledge relies on Schwartz for disclosure of a plurality of grooves and a plurality of holes. According to Examiner Cumberledge, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device disclosed in Martin with a plurality of grooves and a plurality of tunnels wherein the tunnel openings intersect one of the grooves formed on the outer surface of the rod in order to arrive at the claimed invention. Applicant respectfully traverses this rejection with respect to the above-listed claims.

Referring to Fig. 1, Martin discloses a pair of holding rods 4a, 4b extending laterally on either side of a patient's spinous process. The rods 4a, 4b being connected to anchoring components 1, 2, 3 for

anchoring the holding rods 4a, 4b to the patient's vertebrae via coupling means 5a, 5b, 6a, 6b, 7a, 7b. The rods 4a, 4b being surrounded by at least one coil spring 21a, 21b, 22a, 22b, 23a, 23b, 24a, 24b interposed between the anchoring components 1, 3. Each coil spring 21a, 21b, 22a, 22b is interposed between the anchoring components of two different vertebrae and have one end connected to one anchoring component for one vertebra and the other end connected to another anchoring component for another vertebra. Springs 21a, 22a, 23b, 24b are compression springs while springs 21b, 22b, 23a, 24a are extension springs. The ends of the springs are mounted with respect to the anchoring component so as to communicate a torsional moment to the corresponding vertebra. To achieve this, the free end of the spring is inserted into a radial drilling 28 formed in a ring 29, which are secured via screws 32 to the rods 4a, 4b. In this manner, the rods 4a, 4b are able to exert elastic forces onto the anchoring components in order to maintain the vertebrae in a corrected position.

Referring to Figs. 6-10 and 12, Schwartz discloses a flexible tubular member 20 for use as a catheter, guidewire, catheter sheath or drug infusion catheter/guidewire. The flexible tubular member 20 is in the form of a metal tube 50 including a plurality of slots 52. As best shown in Fig. 10, the slots 52 may extend helically about the tube 50. Alternatively, as best shown in Fig. 9, the slots 52 may extend longitudinally through the tube 50.

Applicant respectfully submits that any combination of Martin in view of Schwartz in further view of Schwartz would still not disclose each and every limitation of independent claim 15.

Independent claim 15 is directed to a connection unit for use in bony fixation and recites, as follows:

a first bone coupling assembly; and a longitudinal solid metal rod having an outer surface, including: a first end received by and coupled to the first bone

coupling assembly; a second end; and a substantially cylindrical center section located between and coupled to the first end and the second end, **the center section including a plurality of grooves formed in the outer surface of the rod, and a plurality of tunnels formed in the center section of the rod, each tunnel including a pair of diametrically opposed openings on the outer surface of the rod, wherein the tunnel openings intersect one of the grooves formed in the outer surface of the rod.** (Emphasis Added)

Examiner Hoffman is thanked for the courtesy extended during the In-Person Examiner Interview held on June 18, 2009. Per our discussion, Applicant respectfully submits that there is no disclosure, teaching, or suggestion in either Martin or Schwartz of a longitudinal metal rod including a substantially cylindrical center section wherein the center section includes a plurality of grooves and a plurality of tunnels. That is, no combination of Martin or Schwartz would disclose, teach or suggest a longitudinal metal rod having a plurality of grooves and a plurality of tunnels. Rather, at the most, Martin discloses a solid flexible longitudinal rod. Schwartz, at the most, discloses a hollow, flexible catheter tube wherein the catheter tube is made flexible by forming a plurality of slots therein. The slots extending either helically or longitudinally through the catheter tube. At the most, the combination of Martin and Schwartz discloses a rod including a plurality of helical slots or a plurality of longitudinal slots. No combination of Martin in view of Schwartz would disclose incorporating both a plurality of grooves and a plurality of tunnels in the center section of a solid metal rod.

Furthermore, even assuming arguendo that the combination of Martin in view of Schwartz did disclose a longitudinal metal rod including a substantially cylindrical center section wherein the center section includes a plurality of grooves and a plurality of tunnels, **Applicant respectfully submits that there is no disclosure, teaching, or suggestion in either Martin or Schwartz that each of the tunnels includes a pair of diametrically opposed openings that intersect one of the grooves such that the**

diametrically opposed openings of the tunnels intersect one of the grooves formed in the outer surface of the rod. According to Examiner Cumberledge, incorporating intersecting grooves and tunnels would necessarily require the tunnels to intersect the grooves. Per our discussion, and as demonstrated during the In-Person Examiner Interview, such assumption is not correct.

Therefore, it is respectfully submitted that no combination of Martin in view of Schwartz in further view of Schwartz would result in a connection unit including all of the limitations of independent claim 15 of the present application. Therefore, it is respectfully submitted that neither Martin nor Schwartz, either alone or in combination, disclose, teach, or suggest all of the limitations of independent claim 15. Accordingly, Applicant respectfully requests withdraw of any rejection of claim 15 based upon obviousness over Martin in view of Schwartz.

Furthermore, it is respectfully submitted that Examiner Cumberledge has not identified any reason why a person of ordinary skill in the art would combined Martin with Schwartz other than it would teach all of the elements of independent claim 15. (*See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. _____ (2007) “[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently known, in the prior art ... important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.”) It is respectfully submitted that without the benefit of the Applicant’s disclosure, it would not be obvious for one of ordinary skill in the art to redesign the rod of Martin to include a plurality of helical slots and a plurality of longitudinal slots as disclosed by the catheter of Schwartz. In fact, this is contrary to the explicit teachings of Schwartz, which explicitly discloses that the catheter tube include either helical slots or longitudinal slots. (*See Tec Air, Inc. v. Denso Manufacturing*

Michigan Inc., 192 F.3d 1353 (Fed. Cir. 1999) “[t]here is no suggestion to combine ... if a reference teaches away from its combination with another source ... ‘A reference may be said to teach away when a person of ordinary skill, upon reading of the reference ... would be lead in a direction divergent from the path that was taken by the applicant.’”)

Therefore, it is respectfully submitted that contrary to Examiner Cumberledge’s assertion, it would not be obvious for one of ordinary skill in the art to redesign the Martin rod to include a plurality of helical slots and a plurality of longitudinal slots as disclosed by Schwartz in order to arrive at the invention of independent claim 15. Thus, it is respectfully submitted that claim 15 is allowable over Martin and Schwartz for at least this reason as well. Withdrawal of this rejection and allowance of independent claim 15 is respectfully requested.

Based upon each of the above-listed arguments, Applicant respectfully submits that claim 15 is allowable over Martin and Schwartz. Withdrawal of this rejection and allowance of independent claim 15 is respectfully requested.

Furthermore, as claims 16, 18, 22 and 23 all depend from independent claim 15, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 16, 18, 22 and 23 is also respectfully requested.

INDEPENDENT CLAIM 24

Independent claim 24 and claims 25, 27 and 31-38, which are dependent therefrom, were rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of Schwartz. Specifically, Examiner Cumberledge indicated Schwartz discloses each and every limitation of independent claim 24

but for the center section including a plurality of grooves formed in the outer surface of the rod and a plurality of tunnels formed in the center section of the rod, each tunnel including a pair of diametrically opposed openings on the outer surface of the rod, wherein the tunnel openings intersect one of the grooves formed on the outer surface of the rod. That is, as admitted by Examiner Cumberledge, Schwartz does not disclose a connection unit including a plurality of grooves and a plurality of tunnels wherein the tunnel openings intersect one of the grooves formed on the outer surface of the rod. Rather, Examiner Cumberledge stated that Schwartz discloses an embodiment containing a plurality of grooves and another embodiment containing a plurality of holes. According to Examiner Cumberledge, combining the plurality of grooves and the plurality of tunnels would necessarily result in the tunnels intersecting the grooves. Applicant respectfully traverses this rejection with respect to the above-listed claims.

Referring to Figs. 6-10 and 12, Schwartz discloses a flexible tubular member 20 for use as a catheter, guidewire, catheter sheath or drug infusion catheter/guidewire. The flexible tubular member 20 is in the form of a metal tube 50 including a plurality of slots 52. As best shown in Fig. 10, the slots 52 may extend helically about the tube 50. Alternatively, as best shown in Fig. 9, the slots 52 may extend longitudinally through the tube 50.

Applicant respectfully submits that Schwartz does not disclose each and every limitation of independent claim 24. Independent claim 24 is directed to a longitudinal metal rod for use in bony fixation and recites, as follows:

a first end; a second end; and a substantially cylindrical center section located between and coupled to the first end and the second end, **the center section including a plurality of grooves formed in the outer surface, and a**

plurality of tunnels formed in the center section, each tunnel including a pair of diametrically opposed openings on the outer surface, wherein the tunnel openings intersect one of the grooves formed in the outer surface. (Emphasis Added)

Assuming arguendo that one would look to the catheter art (a tool used temporarily within a patient's body) to design a longitudinal metal rod for use in bony fixation, Applicant respectfully submits that there is no disclosure, teaching, or suggestion in Schwartz of a longitudinal solid metal rod including a substantially cylindrical center section wherein the center section includes a plurality of grooves and a plurality of tunnels. Schwartz does not disclose, teach or suggest a longitudinal solid metal rod having a plurality of grooves and a plurality of tunnels. Rather, as admitted by Examiner Cumberledge, Schwartz disclose a hollow flexible catheter tube including either a plurality of helical slots or a plurality of longitudinal slots. Contrary to the Examiner Cumberledge's assertion, it is respectfully submitted it would not be obvious to one of ordinary skill in the art to combine the helical slots formed in one embodiment of the catheter tube as disclosed by Schwartz with the longitudinal slots formed in another embodiment of the catheter tube as disclosed by Schwartz. In fact, such combination is contrary to the explicit teachings of Schwartz, would explicitly disclose that the catheter tube include either helical slots or longitudinal slots.

Furthermore, even assuming arguendo that one of ordinary skill in the art would combine the helical slots formed in one embodiment of the catheter tube as disclosed by Schwartz with the longitudinal slots formed in another embodiment of the catheter tube as disclosed by Schwartz, **Applicant respectfully submits that there is no disclosure, teaching, or suggestion in Schwartz that each of the tunnels include a pair of diametrically opposed openings that intersect one of the grooves such that the diametrically opposed openings of the tunnels intersect one of the grooves**

formed in the outer surface. As demonstrated during the Examiner Interview, contrary to Examiner Cumberledge's statement, incorporating intersecting grooves and tunnels would not necessarily require the tunnels to intersect the grooves.

In addition, it is respectfully submitted that Examiner Cumberledge has not identified any reason why a person of ordinary skill in the art would incorporate a plurality of helical slots and a plurality of longitudinal slots as disclosed in Schwartz other than it would teach all of the elements of independent claim 24. Especially when such combination is contrary to the explicit teachings of Schwartz, which explicitly discloses that the catheter tube include either helical slots or longitudinal slots. (*See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. _____ (2007) “[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently known, in the prior art ... important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.”) It is respectfully submitted that without the benefit of the Applicant's disclosure, it would not be obvious for one of ordinary skill in the art to redesign the catheter tube of Schwartz to include both a plurality of helical slots and a plurality of longitudinal slots.

It is respectfully submitted that Schwartz does not disclose teach, or suggest all of the limitations of independent claim 24. Accordingly, Applicant respectfully requests withdraw of any rejection of claim 24 based upon obviousness over Schwartz.

Furthermore, as claims 25, 27 and 31-38 all depend from independent claim 24, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 25, 27 and 31-38 is also respectfully requested.

CONCLUSION

Based upon the above-listed amendments and remarks, Applicants respectfully submit that the present application, including claims , 1, 2, 4-8, 10, 15, 16, 18, 22-25, 27 and 31-39, is in condition for allowance and such action is respectfully requested.

A fee of \$1,330.00 is believed due with this submission - a fee of \$1,110.00 for the filing of a three month extension of time and a fee of \$220.00 for the addition of one new independent claim in excess of three. The Commissioner is authorized to charge this and any other fee which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

Date: June 22, 2009

Respectfully submitted,

/Giuseppe Molaro/
Giuseppe Molaro
Registration No. 52,039

For: Brian M. Rothery
Registration No. 35,340
Attorney for Applicants
Stroock & Stroock & Lavan LLP
180 Maiden Lane
New York, New York 10038
(212) 806-6114